Aclaris Therapeutics Announces Positive Results from Phase 1 Multiple Ascending Dose Trial of ATI-2138, an Investigational Oral Covalent ITK/JAK3 Inhibitor

September 18, 2023

– Preliminary Data Support Progression to Phase 2a Proof of Concept Trials in T cell-mediated Autoimmune Diseases –

WAYNE, Pa., Sept. 18, 2023 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced positive results from ATI-2138-PKPD-102, a Phase 1 Multiple Ascending Dose (MAD) trial of the investigational compound ATI-2138.

Preliminary data from the MAD trial demonstrated:

- that ATI-2138 was generally well tolerated at all doses tested in the trial;
- that ATI-2138 had dose proportional pharmacokinetics (PK); and
- a dose-dependent inhibition of both ITK and JAK3 exploratory pharmacodynamic (PD) biomarkers, with near maximal inhibition achieved at the 30 mg total daily dose.

Based on these results, Aclaris will progress this program into a Phase 2a proof of concept study in patients with ulcerative colitis, its previously announced intended first clinical development target, and anticipates initiation of the trial in early 2024. Aclaris is also exploring the potential of conducting a second proof of concept trial in an additional T cell-mediated autoimmune disease.

ATI-2138-PKPD-102 was a two-week Phase 1 MAD trial to investigate the safety, tolerability, PK and PD of ATI-2138 in healthy volunteers. The study enrolled 60 healthy subjects across 6 dosing cohorts ranging from 10 to 80 mg of total daily doses, with 8 active/2 placebo controlled per arm. No serious adverse events were reported. The most common adverse events in subjects treated with ATI-2138, and the only events occurring in more than 1 subject, were headache (assessed as mild, 2 subjects on 5 mg BID, 1 on 40 mg BID) and diarrhea (assessed as mild, 2 subjects on 5 mg BID).

“The advancement of ATI-2138 to proof-of-concept stage of development marks yet another example of the strength of our world class discovery group and the KINect® platform,” stated Doug Manion, M.D., Aclaris’ Chief Executive Officer. “It is a rarity for a biotech company of our size to be armed with a productive discovery engine and expertise that rivals larger pharmaceutical companies.”

Continued Manion, “With so much unmet medical need remaining in immuno-inflammatory diseases such as ulcerative colitis, it is gratifying for all of us at Aclaris to progress the development of ATI-2138 for patients who remain underserved by the existing treatment options for the disease. Additionally, we look forward to the data from our two most advanced programs – zunsemetinib (ATI-450) in rheumatoid arthritis and ATI-1777 in atopic dermatitis – expected later this year.”

Aclaris has made available a related presentation for the ATI-2138 MAD trial data which can be found on the “Investors” section of its website, www.aclaristx.com.

About ATI-2138

ATI-2138 is an investigational oral covalent ITK/JAK3 inhibitor that is being developed as a potential therapeutic option across a variety of T cell-mediated diseases. ITK is a T cell receptor activated kinase involved in driving T cell effector functions while JAK3 is a non-receptor tyrosine kinase responsible for the signal transduction of common gamma receptor cytokines, IL-2, IL-4, IL-7, IL-9, IL-15, and IL-21. In blocking both T cell receptor function and cytokine signaling, ATI-2138 has potential utility in T cell driven diseases. ATI-2138 is currently in clinical development and its safety and efficacy has not been evaluated by regulatory authorities.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “anticipate,” “believe,” “expect,” “intend,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Aclaris’ current beliefs and expectations. These forward-looking statements include Aclaris’ expectations regarding the timing of the Phase 2a trial of ATI-2138 in ulcerative colitis as well the potential future opportunities for the clinical development of ATI-2138, and the timing of reporting results from other clinical trials. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris’ reliance on third parties over which it may not always have full control, Aclaris’ ability to enter into strategic partnerships on commercially reasonable terms and other risks and uncertainties that are described in the Risk Factors section of Aclaris’ Annual Report on Form 10-K for the year ended December 31, 2022 and other filings Aclaris makes with the U.S. Securities

and Exchange Commission from time to time. These documents are available under the “SEC Filings” page of the “Investors” section of Aclaris’ website at www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Aclaris Therapeutics Contact:

Robert A. Doody Jr.
Vice President, Investor Relations
484-639-7235
rdoody@aclaristx.com

Source: Aclaris Therapeutics, Inc.